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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,873	08/26/2002	Raymond E. Ideker	UAB- 15602/22	8083
25006	7590	09/30/2005	EXAMINER	
GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C			JASTRZAB, JEFFREY R	
PO BOX 7021			ART UNIT	
TROY, MI 48007-7021			PAPER NUMBER	

3762

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,873

Applicant(s)

IDEKER ET AL.

Examiner

Jeffrey R. Jastrzab

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 2/2/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 15-25 and 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 26-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 12/28/04 have been fully considered but they are not persuasive. As stated in the Advisory Action, the amendment does not serve to overcome the art rejection of record. Applicants argue the concept of a passive conductor, however this remains unclaimed as noted in the prior office action. For example, In Claim 1, the at least a first conductor, although not specifically stated as being connected to the stimulus generator, could be connected as currently claimed since an open ended claim format is used, i.e. "comprising" in the preamble, which would read on the various optional lead configurations of Bonner et al. noted previously.

Applicant additionally argues that no statement can be found in Bonner et al. that indicates that there is conduction through myocardial tissue. This is not persuasive. As those in the art will appreciate, when a discharge is given in the heart, either a monopolar, bipolar or multipolar electrode configuration is selected to affect the field transfer through the myocardium. In an instance as created by the multiple lead configurations in column 4 lines 28-35 of Bonner et al. the discharge is given in a "bipolar" mode. Also, in this regard, the term "in contact" is broad enough to encompass "electrical contact" which would be made whether in direct contact with the myocardium or through the blood pool. In either instance, the return electrode(s) whether on the can or on additional leads (per column 4 of Bonner et al.) would read on at least a first conductor as currently claimed since direct contact is not required by the claim language at present.

It may be helpful to address the fact that the passive conductor of Applicant's invention is not connected to the pulse generator in a typical return electrode fashion, but is instead is its own entity in the system and electrically unconnected to the pulse generator via a return loop. Currently, this concept is not conveyed in the claim and not taught in the Bonner et al. device as in that system the leads are electrically and physically connected together.

Claim Rejections - 35 USC § 112

Claims 1-14 and 26-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 1, "the conductor" lacks antecedence in line 8, in line 11 and line 16. In line 14, "at least one electrical conductor" is vague as it is not clear whether this is the "at least a first conductor" presented earlier, or a different conductor. The statement in the positioning clause of claim 1 regarding the potential difference is confusing. In particular, it is unclear how the potential difference between the two contacts is affected relative to the discharge of the generator. It would appear that the potential difference would be between the intracavitarily disposed electrode and the (first) electrode associated with the "at least a first conductor".

In Claim 26, multiple instances of "the electrically conductive contacts" lack antecedence per se as does "the conductor in the penultimate line.

Claim Rejections - 35 USC § 102

Claims 1-14 and 26-40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bonner et al., US 5,968,086.

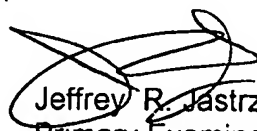
Applicants argue that Bonner does not disclose conduction through myocardial tissue to a passive conductor assembly. However, the claims do not specifically call for a passive assembly. For example, Claim 1 requires an intracavitarily disposed electrode and at least one conductor with first and second contacts thereon. The claim is broad enough to allow one to read a single lead with a defibrillation/cardioversion electrode and 2 pacing electrodes with respective conductors as the electrode and first conductor as claimed, but even if the intracavitarily electrode were read to be different structurally from the "first conductor", Bonner still meets the claim. Note column 4, lines 28-36, wherein alternate cardioversion electrodes can be disposed on separate leads or on the housing. In the latter embodiments, electrodes on the housing would provide passive return electrodes for the cardioversion pulses originating in the lead(s) placed intracavitarily, e.g. the Figure 2 lead, which is the standard operation in a monopolar, i.e. not bipolar, stimulation arrangement with the housing being the "passive" return electrode. This stimulation clearly goes "through" myocardial tissue as claimed. Alternatively, it is inherent that in a bipolar cardioversion mode, the "separate leads" would be used as the "passive" return electrodes, thus providing an instance wherein an intracavitarily-disposed electrode delivers a stimulus to first and second contacts of a separate lead.

As such, Applicants arguments are not deemed to be persuasive. This rejection is hereby made FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Jastrzab whose telephone number is (571) 272-4947. The examiner can normally be reached on Monday - Wednesday 5:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey R. Jastrzab
Primary Examiner
Art Unit 3762
4/11/05